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09/930,104	08/14/2001	Allan Leslie Friedman	2640/1G826US1	9867

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Alphonso A. Collins
Darby & Darby, P.C.
805 Third Avenue
New York, NY 10022

EXAMINER	
WEST, JEFFREY R	

ART UNIT	PAPER NUMBER
2857	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/930,104	FRIEDMAN ET AL.	
	Examiner	Art Unit	
	Jeffrey R. West	2857	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-45* is/are pending in the application.

4a) Of the above claim(s) *33-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 January 2001* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 6, 22, and 23 are objected to because of the following informalities:

In claim 6, lines 4-5, to avoid problems of antecedent basis, "the drive current and the drive voltage" should be ---the initial drive current level and the initial drive voltage level---.

In claim 6, line 6, to avoid problems of antecedent basis, "the impedance data" should be ---the impedance magnitude data---.

In claim 22, line 6, to avoid problems of antecedent basis, "the impedance data" should be ---the impedance magnitude data---.

In claim 23, line 11, to avoid problems of antecedent basis, "lower level" should be ---lower drive level---.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 6-16 and 22-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is considered to be vague and indefinite because it recites "comparing at least one of a magnitude of a lowest impedance of the hand piece/blade". Claim 1,

however, only determines one value of impedance, specifically, "impedance magnitude data". Therefore, since only one value of impedance is obtained, it is unclear as to what "a lowest impedance" refers (i.e. lowest as compared to what?). Claim 22 is rejected as being vague and indefinite for also containing a limitation of "a lowest impedance" without any previous limitations that indicates to one having ordinary skill in the art as to what the relative term "lowest" refers.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, for several reasons.

First, lines 3-7 contain a limitation for determining "if impedance data at a lower drive level than a previous drive level reveals a minimum impedance magnitude which is less than a minimum impedance magnitude obtained at a higher drive level than the previous drive level"

In this section it is unclear to what "a lower drive level than a previous drive level" refers. Parent claim 1 already recites a limitation for "applying a drive signal having an initial drive current level and an initial drive voltage level" and therefore it is unclear to one having ordinary skill in the art whether the "previous drive level" refers to the drive levels presented in claim 1, or to a separate drive level. If the limitation for "a previous drive level" is a drive level separate from the levels of parent claim 1, the claim as written would require the comparison between three drive levels, "a lower drive level", "a previous drive level" and "a higher drive level".

It is also unclear to one having ordinary skill in the art as to what the "minimum impedance magnitude" refers. As claimed, impedance data at a lower drive level

would be revealing a minimum impedance magnitude which is then compared to a minimum impedance magnitude obtained/revealed at a higher drive level. However, since there is no indication that a plurality of impedance data values are obtained at each of the lower and higher drive levels, it is unclear to what a "minimum impedance magnitude" at each of these levels, would refer. Similar problems of clarity exist with respect to the recitation of a "minimum impedance" in lines 11 and 12 of claim 7.

Line 9 of claim 7 then makes a determination based on "a lower drive level than the previous drive level". In this recitation, it is unclear whether "a lower drive level than a previous drive level" is the same as "a lower drive level than a previous drive level" presented in claim 3, or if this level is a separate drive level not earlier presented.

Claim 7 is also considered to be vague and indefinite because it recites "if impedance data at a lower excitation level than the previous drive level reveals one of an unchanged minimum impedance magnitude". This limitation is considered to be vague and indefinite because it is unclear to one having ordinary skill in the art as to what impedance magnitude is unchanged, what it is unchanged with respect to, and over what type of interval it is unchanged.

Claim 23 is rejected as being vague and indefinite for the same reasons mentioned above, because it includes limitation similar to that of claim 7.

Claim 23 is further rejected under 35 U.S.C. 112, second paragraph, because it recites the confusing language of "a higher minimum impedance." It is suggested that "a higher minimum impedance" be changed in a manner similar to claim 7.

Claims 13 and 14 are rejected under 35 U.S.C. 112, second paragraph because in the limitation for calculating "differences between impedance magnitudes" it is unclear to which magnitudes the limitation is referring. For example, parent claim 7 includes "a minimum impedance magnitude which is less than a minimum impedance magnitude obtained at a higher drive level" as well as "an unchanged minimum impedance magnitude or a minimum impedance at the lower drive level which is higher than the minimum impedance magnitude of the hand piece/blade obtained at the higher drive level." Because several impedances are defined, it is unclear to one having ordinary skill in the art what impedance magnitudes are having differences calculated. Claims 29 and 30 are rejected for similar reasons because they contain similar limitations. Further, claims 29 and 30 recite, "all measured impedance magnitudes" while none of the previously mentioned magnitudes are defined as being "measured".

Claims 8-12, 15, 16, 24-28, 31, and 32 are rejected under 35 U.S.C. 112, second paragraph, because they incorporate the lack of clarity present in their respective parent claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claim 1, 2, 4, 6, 17, 18, 20, and 22, as may best be understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,042,460 to Sakurai et al. in view of JP Patent No. 06-003305 to Senda et al.

Sakurai discloses an ultrasonic treating apparatus with a device for inhibiting drive when the ultrasonic element is determined to be defective comprising applying a drive signal to an ultrasonic hand piece/blade using an ultrasonic generator including initial current and voltage drive levels (column 4, lines 17-30), obtaining impedance magnitude data for the hand piece/blade while continuously driving the hand piece/blade with the drive signal (column 4, lines 31-34) comparing the impedance data to a known value to determine whether the impedance data is within acceptable limits (column 4, lines 35-39) and if the impedance is within acceptable limits, displaying a message on a display of the generator (column 4, lines 40-42).

As noted above, the invention of Sakurai teaches many of the features of the claimed invention and while the invention of Sakurai does teach determining incorrect operation of transducer device, Sakurai discloses determining incorrect

operation due to degradation of the device rather than determining a physical defect that causes the incorrect operation.

Senda teaches a method for non-destructively inspecting a piezoelectric element for a micro-crack comprising obtaining impedance data for a known/ideal element (0013, lines 1-4) applying a drive signal for exciting the piezoelectric element over a predetermined frequency range and obtaining impedance magnitude and impedance phase data of the tested element (0021, lines 1-13), at a plurality current and voltage excitation levels (0010), and comparing the impedance of the element under test to the known element impedance data to determine the correctness of operation (0021, line 13 to 0022, line 7 and 0028). Senda also teaches comparing a magnitude of a lowest impedance (i.e. impedance at resonance) (0019) to the expected waveform to determine non-linearity (0010, 0025, and 0028).

It would have been obvious to one having ordinary skill in the art to modify the invention of Sakurai to teach a method for determining a crack in the device as compared to a known/ideal device, as taught by Senda, because the combination would have provided a method for determining the occurrence of a physical defect thereby allowing the user to correctly diagnose and correct the problem and, as suggested by Senda, provided precise diagnostics quickly, automatically, and without destroying the device under test (0005-0007).

Although the invention of Sakurai and Senda discloses performing the comparison to determine a crack in the transducer rather than the blade itself, since the blade and the transducer are attached a change in impedance due to a crack in

the blade would also correspond to the change in impedance observed by the current method (See, for example, page 4, lines 7-16 of the Background of the instant invention that describes the grouped frequency response of the transducer and blade and the correlation between the electric parameters of the transducer and the blade response). Therefore, the combination of Sakurai and Senda operates in a method that determines the change in impedance indicating a crack in the transducer or the connected blade.

6. Claims 3, 5, 19, and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sakurai in view of Senda and further in view of U.S. Patent No. 6,019,775 to Sakurai (Sakurai '775).

As noted above the invention of Sakurai and Senda teaches many of the features of the claimed invention including exciting the hand piece across a predefined frequency range and obtaining impedance data at a plurality of excitation levels, but does specify that the frequency range be from 50 to 60 kHz or that the excitation levels be in the range of 5mA to 50mA.

Sakurai '775 teaches an ultrasonic operation apparatus for performing treatment through utilization of an ultrasonic oscillator comprising a handpiece, serving as a surgical tool, and an apparatus body including a power source unit for supplying electric power to the handpiece (abstract). Sakurai '775 teaches that the handpiece includes a signal generating unit for generating a signal corresponding to a resonant frequency inherent in the ultrasonic element and the probe (abstract). Sakurai '775

also teaches that in ultrasonic surgery tools the oscillator is designed to generate a resonant frequency corresponding to the specific handpiece (column 1, lines 31-47) as well as that the excitation current of the specific handpiece varies based upon the oscillator employed (column 9, lines 41-56).

It would have been obvious to one having ordinary skill in the art to modify the invention of Sakurai and Senda to include sweeping across a predetermined frequency range of 50 to 60 kHz and exciting the handpiece at a current in the range of 5mA to 50mA because Sakurai suggests that each handpiece requires a different frequency sweep range (column 1, lines 31-47) and excitation current (column 9, lines 41-56) based upon the specific makeup of the device being used. Therefore one with ordinary skill in the art would select whatever range is required for the user's specific device, such as 50 to 60 kHz or 5mA to 50mA, as necessary to implement the specific device in its required operation. (See also, for example, U.S. Patent No. 6,391,042 to Cimino, column 1, lines 28-37, U.S. Patent No. 5,406,503 to Williams Jr. et al., column 3, lines 50-60, and U.S. Patent No. 6,387,109 to Davidson et al., column 5, lines 6-26, which teach different ultrasonic devices requiring different frequency ranges and excitation currents for their individual operation.)

Response to Arguments

7. Applicant's arguments with respect to claims 1-32 have been considered but are moot in view of the new ground(s) of rejection.

The following arguments, however, are noted.

It is first noted that Applicant has indicated that in response to the rejection of claims 1-32 under 35 U.S.C. 112, second paragraph, "Applicants have amended the claims in a manner which is believed to resolve each specific rejection", but as noted above, several of the rejections, specifically with respect to claims 7 and 23, have not been overcome.

Applicant first argues that "with reference to Fig. 3 of the *Sakurai* et al. patent, an 'impedance detection circuit 11' is shown separate from the 'drive circuit 5.' In addition, a 'change over circuit 6' is also shown. With this configuration, the system disclosed in *Sakurai* et al. can only measure and conclude whether the probe is 'good or bad' prior to, or after, operation of the scalpel. In this system, the change over circuit 6 must be used to switch between the impedance detection circuit 11 and the drive circuit 5 in order to perform impedance measurements or to drive the hand piece with the drive signal. As a result, the hand piece of the *Sakurai* et al. patent will be activated even if it cracked, and will continue to be driven even if it becomes cracked during use. This is a dangerous mode of operation. In contrast, the impedance circuit and the detection circuit of the present invention are combined. As a result, the hand piece/blade of the claimed system may be continuously driven, while the impedance measurements are being performed . . . This ability is reflected in claims 1 and 17 as amended, wherein the hand piece/blade is continuously driven with the drive signal while the impedance magnitude data for the had piece/blade is obtained. For at least this reason,

Applicants respectfully assert that the *Sakurai* et al. patent fails to teach the invention as set forth in amended claims 1 and 17."

While the Sakurai reference has been reconsidered and new sections of the reference have been cited in the body of the rejection, the Examiner also notes that while the invention of Sakurai does include a "drive circuit 5" that is controlled by a "switch drive circuit 8", the impedance detection circuit "11" also contains a power supply "12" that continuously applies a drive signal during the impedance measurement. Specifically, Sakurai states:

> "With the switch 13 turned ON, a voltage on the AC power source 12 is created across the output terminals 11a, 11b via the current detector 14. The voltage is applied to the ultrasonic vibration element 2 via the normally closed contacts of the switches 7a, 7b in the changeover circuit 6. As a result, a current I flows through the ultrasonic vibration element 2 and detected by the current detector 14. The result of detection is sent to the computing section 16. With the switch 13 turned ON, a voltage V on the AC power source 12 is detected by the voltage detector 15 and a result of detection is sent to the computing section 16. The computing section 16 divides the voltage V by the current I to find an impedance Z of the ultrasonic vibration element 2 at step S3. The impedance Z thus found is fed to the CPU 10. The CPU 10 ascertains whether the impedance Z is within a predetermined range, such as $Z_1 \leq Z \leq Z_2$, at step S4. Here Z_1 and Z_2 denote the setting values. If the impedance Z is a proper value, the CPU 10

determines that the ultrasonic vibration element 2 is good at step 5" (column 4, lines 17-34).

Therefore, the newly added limitation for "obtaining impedance magnitude data for the hand piece/blade while continuously driving the hand piece/blade with the drive signal" is met by the invention of Sakurai.

Applicant then argues that "the *Sakurai* et al. patent fails to disclose the concept of 'differentiating between burdened and cracked ultrasonically tuned blades.' *Sakurai* et al. only sets a 'go-no-go criteria' (i.e. determine whether the scalpel can be safely activated or not) for the system and fails to mention the determination of whether the prove 4 (i.e., the blade as illustrated and claimed in the present invention) is good or cracked. In contrast amended claims 1 and 17 are directed to determining whether the blade is okay, i.e., the blade is not cracked or simply burdened with gunk. Accordingly, for this additional reason, Applicants respectfully asserts that the *Sakurai* et al. patent fails to teach the present claimed invention."

The Examiner asserts that the only limitation in claims 1 and 17 that refer to this feature is a general "method for detecting gunked and cracked ultrasonically tuned blades in an ultrasonic surgical system" listed in the preamble.

A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead,

the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Secondly, this limitation in the preamble does not claim any method for "differentiating between burdened and cracked ultrasonically tuned blades" but only states that the method can be used for "detecting gunked and cracked ultrasonically tuned blades".

Applicant then presents similar lines of argument with respect to the teachings of Senda and Sakurai '775 for not teaching "obtaining impedance magnitude data for [a] hand piece/blade while continuously driving the hand piece/blade with [a] drive signal."

As noted above, the invention of Sakurai does teach this feature, and therefore these arguments are not considered to be persuasive.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure.

U.S. Patent No. 6,391,042 to Cimino teaches a pulsed ultrasonic device and method as well as the conventional operating range of 20kHz to 60kHz.

U.S. Patent No. 5,406,503 to Williams Jr. et al. teaches a control system for calibrating and driving ultrasonic transducers including a power amplifier and

transformer section that provides a maximum driving voltage of about 380 volts RMS with a maximum current of about 10 mA RMS.

U.S. Patent No. 6,387,109 to Davidson et al. teaches methods and a device for improving blood flow to the heart of a patient including a generator that applies a specific current to acoustically vibrate an assembly in the range of 20kHz to 100 kHz, preferably, 54 kHz to 56 kHz.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. West whose telephone number is (703)308-1309. The examiner can normally be reached on Monday through Friday, 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marc S. Hoff can be reached on (703)308-1677. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0956.

jrw
November 24, 2004

MARC S. HOFF
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800